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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,042

Applicant(s)

TAINTOR, READ ROBERT

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

Newly submitted claims 1-20, directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Reiteration of restriction:

- I. Claims 1-15, drawn to a kit, classified in class 435, subclasses 287.1 and 945.
- II. Claims 16-20, drawn to a method for performing microbiological testing, classified in class 435, subclass 243.

I. The inventions are distinct, each from the other because of the following reasons: Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by hand using a multi-well format. Also with respect to the apparatus or kit, Group II may use an entirely different kit or may be carried out by hand as well. Therefore, the claims are deemed restrictable one group from the other for these reasons.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Miscellaneous and Papers

The drawings filed with the case under 35 USC 113, will be reviewed by the PTO-Draftsperson to determine whether they are acceptable or not and Applicants will be notified of the outcome in the next action. Also the decision dismissing Applicant's

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Request for Refund is noted and Applicant should have received a copy of the decision mailed July 29, 2002. *Power of Attorney document filed 8/14/03 has been received.*

Rejections

II. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

III. Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is rendered vague and indefinite for the recitation of "said broth-cultured-microbial-sample" wherein the term appears to lack antecedent basis. Thus, it is suggested to change "said" within this phrase to --a-- . Also the language "where several different microorganism types may exist and" wherein the language is unclear with respect to what microorganisms are contained by the sample and whether they are viable microorganisms or not? The metes and bounds of the claims can not be determined, therefore. It is suggested to delete the language. It is further suggested to insert a --:-- after "the steps of" at line 3 of claim 16. In addition, the term "said broth", "said microorganisms", and "said microbial source", recited in step a. appear to also lack antecedent basis. Thus, it is suggested to delete "said" at each occurrence in step a. and before "broth" and "microbial source" insert --a--. Also the recitation of "said microbial source's said microorganisms" also lacks antecedent basis in the claim and should be deleted in step b, and replaced with the term --the-- and before "resulting in said broth-cultured-microbial sample" it is suggested to insert --of step a.-- and at the

end of step b. in place of "and" insert a --;-- . Further, at end of step a. it is suggested to delete "and" and insert --;-- too. In step c. the recitations of "said kit plate" and "said microbiological testing media" also lacks antecedent basis and the term "said" should be deleted and with the deletion of "said" before "kit plate" a --a-- should be inserted. Also at the end of step c. the "and" should be deleted and replaced with --;-- . Also in step c. it is suggested to change "with" to --having- for better clarity to define that the "kit plate" comprises a plurality of test chambers. However, the term --comprising-- can be alternatively used if Applicants prefer. In steps d and e. . it is further to delete the "and" and replace with --;-- , respectively for each step. Also in step d. and e. after "microbial-sample" and "said kit plate", respectively in each steps d. e. it is suggested to insert respectively --of step b-- and of step d-- . Also it is suggested to change "sufficient time" to --a period of time-- . In step f. it is suggested to delete "said" before "microbiological testing" because it does not appear to have antecedent basis as presently claimed in step f, since "said kit plate" recited at line 1 of step f. should refer back to --of step e-- . Also the phrase "comprising said" is suggested to be changed to --wherein said testing includes concurrent identification testing and antimicrobial susceptibility testing on one or more different microorganisms in a test chamber of said plurality of test chambers,-- and thus, to further delete "which may involve more than one said microorganism type in the same said test chamber and" . Also it is suggested to delete "rapid said microbiological tests comprising concurrent said identification testing and said antimicrobial susceptibility testing of one to several said microorganism types may be performed without a prior isolation step" and to thus, insert in place thereof in the "whereby" clause after "whereby" the following insertion --said microbiological testing of one or more different microorganisms is performed without an isolation step -- .

Claim 17 is further rendered vague and indefinite for similar usage of language as described above which does not have proper antecedent basis. For example, the recitation of "said broth" is unclear as to which broth is being referred to from claim 36. Therefore, after "said broth" in line 1, it is suggested to insert --of step a.-- and further to delete "with an inoculation of said microbial source" recited on line 2.

Claim 18 is further rendered vague and indefinite for the recitation of "said susceptibility testing media" at line 3, because the term lacks antecedent basis. It is suggested to delete "susceptibility" and after "testing media" insert --of said plurality of test-- and further delete "and several said identification chambers" and replace "testing" at line 4 with --said microbiological testing in step f.--

Claim 19 is further rendered vague and indefinite for the term "significant" and it is suggested to delete this term because it is subjective in its meaning and thus, it is unclear what its intended meaning is in the claim. Also at line 2 it is suggested to delete "made and" because it is uncertain how the concentrations being made because no steps are provided to define how to make the equivalent concentration and further because if the concentration is available for inoculation then it must have been made, so the term really serves no clear intended purpose in the claim and tends to raise a question as to how it is made, per se. Further, it is suggested to delete "un-inoculated" at line 3, because if the "test chambers" are being actively inoculated then they must be "un-inoculated" so therefore, the term is unnecessary. Further, in accordance with above changes it is suggested to insert --plurality of-- before "test chambers" at line 3. Also the step of "produces individual isolated colonies of said microorganisms" is unclear since claim 16 require that testing be performed without an isolation step. It appears that claim 19 may incorporate an isolation step, per se. Therefore, since this is the only main difference between claim 18 and 19 it is suggested to delete claims and

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also because the claim appears to be contradictory to what claim 16 sets forth with respect to a the requirement of testing to be performed without a prior isolation step.

Likewise claim 20 is further rendered vague and indefinite for similar language as discussed above but in addition claim 20 should be canceled because it does not appear to further limit claims 16 and 19. The claim 20 appears to require the same steps required of claims 16 and 19. There is really no limiting step of claim 20 for which to distinguish it clearly from claims 16 and 19.

IV. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

V. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

VI. Claims 16-17 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scholl et al. (A).

VII. Claims are drawn to a method for quickly performing a plurality of microbiological tests comprising: providing a broth for rapid cultivation of microorganisms; providing incubation resulting in a broth-cultured-microbial-sample; providing a kit plate having a plurality of test chambers comprising testing media, providing incubation of the kit plate; and providing testing on the kit plate comprising identification and susceptibility tests. Incubation can be for a short time to generate broth-cultured-microbial-sample.

VIII. Scholl et al. teach a method for quickly performing a plurality of microbiological tests comprising: providing a broth for rapid cultivation of microorganisms; providing incubation resulting in a broth-cultured-microbial-sample; providing a kit plate having a plurality of test chambers comprising testing media, providing incubation of the kit plate; and providing testing on the kit plate comprising identification and susceptibility tests. Incubation can be for a short time to generate broth-cultured-microbial-sample. Note the abstract; col. 4, lines 15-50 and 63; col. 5, lines 35-45; col. 7, line 65; col. 8, lines 10-20; col. 10, lines 22-23, line 58, lines 66-67; col. 11, lines 5-7, lines 10-25, lines 30-40, lines 48-49, lines 52-60, lines 65-67; col. 12, lines 1-55; col. 15-17, all lines; col. 19, lines 9-40; col. 25, lines

15-25; col. 26, lines 44-67; col. 27, lines 15-20; col. 28, lines 30-40; col. 31, lines 19-25, lines 65-66; col. 32, lines 1-20; col. 33, line 38; and col. 34, lines 20-40, for the disclosure of the process steps as discussed above for Scholl et al.

IX. The claims appear to be identical to the cited disclosure of Scholl et al. and thus, are therefore, considered to be anticipated by the teachings of the references. Rapid cultivation appears to be disclosed since long incubation periods indicate cultivation which is not rapid, and because the disclosed method resolves the need of the prior art for cell culture methods which provide for rapid detection and identification in a cost-effective manner. Note col. 4, lines 15-25. However, in the alternative that there is some unidentified claim characteristic which provides for some difference between the claims and the cited prior art then the difference is considered to be so slight as to render the claims obvious over the cited prior art reference. Further, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method for quickly performing a plurality of microbiological tests comprising: providing a broth for rapid cultivation of microorganisms; providing incubation resulting in a broth-cultured-microbial-sample; providing a kit plate having a plurality of test chambers comprising testing media and diluted cultures, providing incubation of the kit plate; and providing testing on the kit plate comprising identification and susceptibility tests. Incubation can be for a short time to generate broth-cultured-microbial-sample as disclosed by Scholl et al. Clearly

Scholl et al. and Rao teach each process step and to provide for rapid cultivation, and steps of incubation, inoculation of a kit plate with the culture sample, further incubation for a short time of kit plate and testing thereof to perform identification and susceptibility tests of microbiologicals. Therefore, to provide for a method using these well known disclosed steps of Scholl et al. is within the skill of an ordinary artisan at the time the claimed invention was made. The claims are rendered in the alternative prima facie obvious over Scholl et al.

X. Claims 16-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao (B).

Claims are discussed above.

Rao teaches a method for quickly performing a plurality of microbiological tests comprising: providing a broth for rapid cultivation of microorganisms; providing incubation resulting in a broth-cultured-microbial-sample; providing a kit plate having a plurality of test chambers comprising testing media, providing incubation of the kit plate; and providing testing on the kit plate comprising identification and susceptibility tests. Incubation can be for a short time to generate broth-cultured-microbial-sample. Note col. 10, lines 20-67 and col. 11, lines 29-60. Further, the limitation of 0.5 McFarland equivalent concentration is disclosed to be used to show good culture growth.

All of the claims appear to be identical to the cited disclosure of Rao, and thus, are therefore, considered to be anticipated by the teachings of the reference. However, in the alternative that there is some unidentified claim characteristic which provides for some difference between the claims and the cited prior art then the difference is

considered to be so slight as to render the claims obvious over the cited prior art reference. Further, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a method for quickly performing a plurality of microbiological tests comprising: providing a broth for rapid cultivation of microorganisms; providing incubation resulting in a broth-cultured-microbial-sample; providing a kit plate having a plurality of test chambers comprising testing media and diluted cultures, providing incubation of the kit plate; and providing testing on the kit plate comprising identification and susceptibility tests. Incubation can be for a short time to generate broth-cultured-microbial-sample as disclosed by Rao. Clearly Rao teaches each process step and to provide for rapid cultivation, and steps of incubation, inoculation of a kit plate with the culture sample, further incubation for a short time of kit plate and testing thereof to perform identification and susceptibility tests of microbiologicals. Therefore, to provide for a method using these well known disclosed steps of Rao is within the skill of an ordinary artisan at the time the claimed invention was made. The claims are rendered in the alternative prima facie obvious over Rao.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.


No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 308-4245. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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September 25, 2003